Guidance for Industry and FDA Staff

Compliance Guide for Cabinet X-Ray Systems

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For questions regarding this document contact Daniel Kassiday at 301-796-5865 or Daniel.Kassiday@FDA.HHS.GOV.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Electronic Products Branch
Division of Mammography Quality and Radiation Programs
Office of Communication, Education, and Radiation Programs

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Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Guidance for Industry and FDA Staff

Compliance Guide for Cabinet X-Ray Systems

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

Manufacturers of cabinet x-ray systems sold in the United States (U.S.) are responsible for complying with the electronic product radiation control provisions of the Federal Food, Drug, and Cosmetic Act (Act), including radiation performance standards [21 U.S.C. 360hh-360ss]. This guide is intended to assist manufacturers of cabinet x-ray systems with meeting the requirements of the Act and applicable federal radiation safety regulations [21 CFR 1020.40, Parts 1000-1005, 1010[1]]. The term 'manufacturers' includes those engaged in the business of manufacturing, assembling, or importing cabinet x-ray systems into the U.S.

The federal radiation safety performance standard for cabinet x-ray systems (performance standard) is found at 21 CFR 1020.40. Cabinet x-ray systems sold in the U.S. are required to comply with all applicable requirements of the performance standard. Before selling a cabinet x-ray system in the U.S., a manufacturer must certify that its product meets the applicable requirements of the performance standard [21 CFR 1010.2]. This certification must be based on a quality control and testing program that is in accordance with good manufacturing practices [21 CFR 1010.2]. Certification of compliance with a foreign

[1] In addition to the requirements implemented through these regulations, manufacturers must comply with other applicable provisions of the Act and regulations, including provisions applicable to the product if it is a medical "device" under the Act (21 U.S.C. 301(h)) or if the product is used in food irradiation (21 CFR Part 179). Discussion of medical device and food irradiation provisions and regulations is beyond the scope of this document.

radiation safety standard can not be substituted for certification of compliance with the U.S. performance standard.

Throughout this guide, relevant sections of the regulation will be cited. This guide does not replace the regulations. Should a conflict between the two arise, the regulations supersede this guide. When the text of a regulation is quoted it will appear in *italics*.

You should direct specific questions to the contact person listed on the coversheet of this guide or in writing to:

Center for Devices and Radiological Health
Office of Communication, Education, and Radiation Programs (HFZ-240)
Electronic Products Branch
10903 New Hampshire Avenue
Silver Spring, MD 20993
Rockville, MD 20850

Phone: 301-796-5710
Fax: 301-847-8502

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device and electronic product regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

1. Definitions

You may find many of the following definitions in 21 CFR 1000.3 or 1020.40(b) (we have provided the specific citations). Some of the definitions are interpretations of terms not specifically defined in the regulations but are based on our experience with electronic products.

Categories of X-Ray Products

This guidance discusses a variety of x-ray categories. Cabinet x-ray systems are subject to the most extensive requirements because cabinet x-ray systems are subject to a specific performance standard [21 CFR 1020.40]. In addition to the performance standard [21 CFR

1020.40], manufacturers of cabinet x-ray systems sold in the U.S. must comply with 21 CFR Parts 1000, 1002, 1003, 1004, 1005, and 1010.

- **Cabinet X-Ray System** [21 CFR 1020.40(b)(3)] *means an x-ray system with the x-ray tube installed in an enclosure (hereinafter termed cabinet) which, independently of existing architectural structures except the floor on which it may be placed, is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. Included are all x-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and in similar facilities. An x-ray tube used within a shielded part of a building, or x-ray equipment which may temporarily or occasionally incorporate portable shielding is not considered a cabinet x-ray system.*

A cabinet x-ray system always includes an x-ray tube installed in a shielded enclosure intended to contain the item being irradiated. The enclosure protects people from the x-rays generated and excludes people from the enclosure's interior. Because the shielding surrounds the volume exposed to x-ray and the shielding is an inherent part of the system, cabinet x-ray systems are sometimes referred to as closed x-ray systems.

Cabinet x-ray systems are primarily used for security screening and industrial quality control. Security applications range from screening baggage at airports to systems used to inspect trucks entering the U.S. Industrial quality control applications include food, circuit board, and tire inspections. There are also a few medical devices that are also cabinet x-ray systems such as x-ray systems used to view tissue samples.

The provisions of the performance standard apply to cabinet x-ray systems designed primarily for inspecting carry-on baggage manufactured or assembled on or after April 25, 1974. Additionally, the performance standard applies to **all** cabinet x-ray systems manufactured or assembled on or after April 10, 1975 [21 CFR 1020.40(a)].

If an x-ray system does not meet all of the criteria of the definition in the regulations, then it is not a cabinet x-ray system. For example, adding shielding to an existing room does not make that room a cabinet because the room is not independent of existing architectural structures. A free-standing shielded room independent of existing architectural structures, excluding the floor, built to house an x-ray tube is subject to the performance standard.

X-ray systems that are **not** cabinet x-ray systems are subject to different reporting requirements [21 CFR 1002.1, Table 1]. The performance standard [21 CFR 1020.40(a)] **does not** apply to:

- systems designed exclusively for microscopic examination of materials;
- systems designed for intentional exposure of humans to x-rays; or
- products that use radioactive material as the source of their radiation.

Other categories of x-ray systems are defined below.

Products intended to produce particulate radiation or x-rays other than diagnostic[2] or cabinet x-ray systems [21 CFR 1002.1, Table 1]

Although the following products are not subject to a mandatory performance standard, the products and manufacturers are subject to regulation under the Act. Manufacturers of x-ray and particle radiation systems sold in the U.S. are responsible for complying with 21 CFR Parts 1000, 1002, 1003, 1004, and 21 CFR 1005.25. When possible, FDA recommends that manufacturers design their products to comply with voluntary consensus radiation safety standards when those standards are available and appropriate for the product.

- **Analytical X-Ray Systems**
  Analytical x-ray systems are those systems that are designed exclusively for the microscopic examination of material. The phrase "exclusively for the microscopic examination of material," refers to x-ray spectroscopy, x-ray diffraction, or x-ray fluorescence. These x-ray systems are usually intended to be operated only in a laboratory setting. An x-ray system is exempt from the performance standard [21 CFR 1020.40(a)] when it is designed exclusively for microscopic examination of material. The performance standard is applicable to systems intended for education (for example teaching x-ray physics) or for industrial quality control used in a manufacturing environment because those uses are not, "exclusively for the microscopic examination of materials."

- **Medical X-Ray Systems**
  Products that are not subject to the cabinet x-ray or diagnostic x-ray standards and that are medical devices are medical x-ray systems. Examples include, but are not limited to, radiation therapy products that use accelerators and veterinary x-ray systems.

- **Industrial X-Ray and Particulate Radiation Systems**
  Products that are not subject to the cabinet x-ray or diagnostic x-ray standards, do not fall into the analytical x-ray or medical x-ray categories, and use x-ray tubes or accelerators to produce ionizing radiation fall into the industrial x-ray or particle radiation category. However, x-ray products that have an industrial purpose and are closed systems are cabinet x-ray systems subject to the performance standard. Examples of industrial x-ray systems include accelerators used for medical device sterilization, open beam systems used for nondestructive testing, open beam systems used for bomb detection, and personnel security screening systems that use x-rays.

Regulatory Terms

- **Accidental radiation occurrence** (ARO) [21 CFR 1000.3(a)] *means a single event or series of events that has/have resulted in injurious or potentially injurious exposure of any person to electronic product radiation as a result of the manufacturing, testing, or use of an electronic product.*

[2] Diagnostic x-ray systems are subject to a specific performance standard, 21 CFR 1020.30.

Reports of an ARO are required by 21 CFR 1002.20. Discussion of this requirement appears in the **Reports and Records** section of this document.

- **Commerce** [21 CFR 1000.3(d)] *means:*
(1) Commerce between any place in any State and any place outside thereof, and
(2) Commerce wholly within the District of Columbia.

  Building a system for your own use at the location where it will be used is not ordinarily considered entry into commerce. Building a system for your company's use and transporting it from one location to another can be commerce.

- **Manufacturer** [21 CFR 1000.3(n)] *means any person engaged in the business of manufacturing, assembling, or importing electronic products.*

- **Model** [21 CFR 1000.3(o)] *means any identifiable, unique electronic product design, and refers to products having the same structural and electrical design characteristics and to which the manufacturer has assigned a specific designation to differentiate between it and other products produced by that manufacturer.*

Cabinet X-Ray System Terms

- **Access panel** [21 CFR 1020.40(b)(1)] *means any barrier or panel which is designed to be removed or opened for maintenance or service purposes, requires tools to open, and permits access to the interior of the cabinet.*

  Any barrier that is designed to be moveable or opened for routine operation is a **door** (defined below), not an access panel.

  Some cabinet x-ray systems have cosmetic covers that conceal electronics but do not allow access to the cabinet when opened. These covers are not access panels unless they are used to prevent access to interior system components that do allow access to the cabinet.

  Tools can be keys or common tools such as screwdrivers and wrenches.

- **Aperture** [21 CFR 1020.40(b)(2)] *means any opening in the outside surface of the cabinet, other than a port, which remains open during generation of x radiation.*

  Apertures are usually holes for routing cables, ventilation, or wiring into or out of the cabinet.

- **Cabinet** [interpreted from 21 CFR 1020.40(b)(3)] means the enclosure that contains an x-ray tube and is intended to contain at least that portion of a material being irradiated, provide radiation attenuation, and exclude personnel from its interior during generation of x radiation. The cabinet is the only space within a cabinet x-ray system where radiation exposure greater than the emission limit [21 CFR 1020.40(c)(1)] is permitted.

- **Door** [21 CFR 1020.40(b)(4)] *means any barrier which is designed to be movable or opened for routine operation purposes, does not generally require tools to open, and permits access to the interior of the cabinet. For the purposes of paragraph (c)(4)(i) of this section, inflexible hardware rigidly affixed to the door shall be considered part of the door.*

  If the barrier is only opened for maintenance and service, then it is an access panel as defined above. However, if the barrier must be moved for the material being irradiated to be placed in or removed from the cabinet as part of routine operations, then the barrier is a door even if tools are needed.

- **Exposure** [21 CFR 1020.40(b)(5)] *means the quotient of dQ by dm where dQ is the absolute value of the total charge of the ions of one sign produced in air when all the electrons (negatrons and positrons) liberated by photons in a volume element of air having mass dm are completely stopped in air.*

- **External surface** [21 CFR 1020.40(b)(6)] *means the outside surface of the cabinet x-ray system, including the high-voltage generator, doors, access panels, latches, control knobs, and other permanently mounted hardware and including the plane across any aperture or port.*

- **Floor** [21 CFR 1020.40(b)(7)] *means the underside external surface of the cabinet.*

- **Ground fault** [21 CFR 1020.40(b)(8)] *means an accidental electrical grounding of an electrical conductor.*

- **Port** [21 CFR 1020.40(b)(9)] *means any opening in the outside surface of the cabinet which is designed to remain open, during generation of x-rays, for the purpose of conveying material to be irradiated into and out of the cabinet, or for partial insertion for irradiation of an object whose dimensions do not permit complete insertion into the cabinet.*

- **Primary beam** [21 CFR 1020.40(b)(10)] *means the x radiation emitted directly from the target and passing through the window of the x-ray tube.*

- **Safety interlock** [21 CFR 1020.40(b)(11)] *means a device which is intended to prevent the generation of x radiation when access by any part of the human body to the interior of the cabinet x-ray system through a door or access panel is possible.*

  One of the two interlocks required on each door must meet very specific requirements (discussed below). [21 CFR 1020.40(c)(4)(i)].

- **X-ray system** [21 CFR 1020.40(b)(12)] *means an assemblage of components for the controlled generation of x-rays.*

- **X-ray tube** [21 CFR 1020.40(b)(13)] *means any electron tube which is designed for the conversion of electrical energy into x-ray energy.*

2. Overview of Requirements for Manufacturers of Cabinet X-Ray Products

To comply with the Act and the regulations [21 CFR Parts 1000 – 1020], manufacturers of Cabinet X-Ray system products must:

- Design and manufacture their products to comply with the performance standard [21 CFR 1020.40].
- Test their products to assure compliance with the performance standard [21 CFR 1010.2(c)]; this test should be an element of a quality control and testing program that is in accordance with good manufacturing practices.
- Certify that their products comply with the requirements of the performance standard [21 CFR 1010.2], based on their quality control and testing program.
- Permanently affix certification and identification labels to their cabinet x-ray system products [21 CFR 1010.2(b) and 1010.3].
- Maintain and preserve test and distribution records and a file of correspondence concerning radiation safety, safety complaints, and inquiries [21 CFR 1002.30 and 1002.31];
- Provide Cabinet X-Ray Product Reports [21 CFR 1002.10] to the Center for Devices and Radiological Health (CDRH), describing compliance of the product design, quality control, and testing program.
- Provide Annual Reports [21 CFR 1002.13] summarizing test data and records to CDRH;
- Report accidental radiation occurrences (i.e., has/have resulted in injurious or potentially injurious exposure) when reasonable grounds exist to suspect an incident has occurred. [21 CFR 1000.3(a) and 1002.20];
- Report radiation safety defects or failure to comply with the performance standard [21 CFR 1003.10];
- Recall (repurchase/refund, repair, or replace) products that have a radiation safety defect or fail to comply with the performance standard [21 CFR 1004].

- Provide all labels, reports, data, specifications, and correspondence in English [21 CFR 1010.2(b) and 1010.3(a)].

- Additionally, cathode ray tube (CRT) video monitors used in a cabinet x-ray system should be certified to meet the requirements of the federal radiation safety performance standard for television receiver products [21 CFR 1020.10].

- Designate an agent in the U.S. if the original manufacturer is not located in the U.S. [21 CFR 1005.25]

The details of these requirements are discussed in other sections of this document.

3. Requirements of the General Federal Radiation Safety Performance Standard

The general performance standard for electronic products [21 CFR Part 1010] applies to cabinet x-ray systems because the specific performance standard for cabinet x-ray systems [21 CFR 1020.40] applies. The general standard contains the requirements for manufacturer certification of compliance to the specific standard as well as requirements for product identification. The general standard also contains the regulations regarding variances and exemptions from the specific standard.

Certification [21 CFR 1010.2]
(a) Every manufacturer of an electronic product for which an applicable standard is in effect under this subchapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under this subchapter.
(b) The certification shall be in the form of a label or tag permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use, unless the applicable standard prescribes some other manner of certification. All such labels or tags shall be in the English language.

(c) Such certification shall be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices. The Director, Center for Devices and Radiological Health may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this subchapter.

Manufacturers of cabinet x-ray system products must certify their products comply with all the applicable requirements of the performance standard [21 CFR 1020.40]. The certification must be in the form of a label or tag permanently affixed to or inscribed on the cabinet x-ray product, and it must be legible, written in English, and readily accessible to view when the product is fully assembled. The certification must be based on a quality

control and testing program which is carried out in accordance with good manufacturing practices. In addition, the certification must be furnished to the dealers or distributors at the time of delivery.

The certification label must contain a statement that the product complies with the applicable performance standard. The regulations do not require specific wording of the certification statement. This label may not be ambiguous about compliance with the performance standard.

FDA does not approve cabinet x-ray products' compliance with the performance standard. Certification is the manufacturer's statement that its product complies with all of the applicable requirements of the cabinet x-ray radiation safety performance standard [21 CFR 1020.40] and the general performance standard [21 CFR Part 1010]. Manufacturers are responsible for assuring the certification is true to the best of their knowledge. This statement of certification must be based on a quality control and testing program that demonstrates that each product manufactured complies with the applicable standard.

FDA can disapprove a manufacturer's quality control and testing program if it is not adequate because it does not assure compliance with the performance standards. Because certification must be based on a test or testing program that shows the product conforms to the standards, a manufacturer cannot certify its products if its quality control and testing program is disapproved. Therefore, if FDA disapproves a quality control and testing program a manufacturer cannot legally sell its products.

Identification [21 CFR 1010.3]
(a) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall set forth the information specified in paragraphs (a)(1) and (2) of this section. This information shall be provided in the form of a tag or label permanently affixed or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the applicable standard. Except for foreign equivalent abbreviations as authorized in paragraph (a)(1) of this section all such labels or tags shall be in the English language.

(a)(1) The full name and address of the manufacturer of the product; abbreviations such as "Co.," "Inc.," or their foreign equivalents and the first and middle initials of individuals may be used. Where products are sold under a name other than that of the manufacturer of the product, the full name and address of the individual or company under whose name the product was sold may be set forth, provided such individual or company has previously supplied the Director, Center for Devices and Radiological Health with sufficient information to identify the manufacturer of the product.

(a)(2) The place and month and year of manufacture:
(i) The place of manufacture may be expressed in code provided the manufacturer has previously supplied the Director, Center for Devices and Radiological Health with the key to such code.

(ii) The month and year of manufacture shall be provided clearly and legibly, without abbreviation, and with the year shown as a four-digit number as follows:

Manufactured: (Insert Month and Year of Manufacture.)

(b) In the case of products for which it is not feasible to affix identification labeling in accordance with paragraph (a) of this section, upon application by the manufacturer, the Director, Center for Devices and Radiological Health may approve an alternate means by which such identification may be provided.

(c) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall provide to the Director, Center for Devices and Radiological Health a list identifying each brand name which is applied to the product together with the full name and address of the individual or company for whom each product so branded is manufactured.

Manufacturers must place identification information on their cabinet x-ray system which is either permanently affixed as a tag or a label or is inscribed on the product. This information must be legible, written in English, and readily accessible to view when the product is fully assembled. The identification information must include:

1. The full name and address of the manufacturer.
    a. If the product is sold under a different name, then the full name and address of the individual or company selling the product may appear instead if information to identify the manufacturer has been previously provided to CDRH in a product report [21 CFR 1002.10] or supplemental report [21 CFR 1002.11].
    b. See 21 CFR 1010.3(a)(1) for the details on acceptable abbreviations in the manufacturer's name.
2. The place of manufacture.
3. The month and year of manufacture.
    a. The month and year must not be abbreviated.

4. Requirements of the Federal Radiation Safety Performance Standard for Cabinet X-ray Systems

Manufacturers are required to certify [21 CFR 1010.2] that their products sold in the U.S. comply with the radiation safety performance standard for cabinet x-ray systems [21 CFR 1020.40]. The applicability of the performance standard is discussed above in the definitions of the terms 'cabinet x-ray system' and 'analytical x-ray system.'

Emission Limit [21 CFR 1020.40(c)(1)(i)]**:** *Radiation emitted from the cabinet x-ray system shall not exceed an exposure of 0.5 milliRoentgen in one hour at any point five centimeters outside the external surface.*

This requirement does not limit the rate of x-ray emission. It limits the total emission possible in any one hour. Consider the factors that will result in the maximum x-ray emission from the external surface of your product when designing your test program. The system must be tested at the settings and operating conditions resulting in the highest output to assure that this limit can not be exceeded [21 CFR 1010.2].

The amount of time x-ray can be on (x-ray on time) in any one-hour period, the duty cycle, is a factor in meeting this requirement. X-ray on time can be limited by physical system properties or interlocks. Total emissions must not exceed an exposure of 0.5 mR in one hour even when x-ray on time is at its maximum.

Cabinet x-ray systems with ports often use lead curtains to reduce the emissions. Most lead curtains are composed of multiple strips of leaded material. These strips of leaded material are deflected as items pass through creating intermittent gaps. A cabinet x-ray system with ports covered by lead curtains must meet the emission limit at the plane of any port even during an hour when items are being loaded into the system as fast as the system allows. A check of the condition of lead curtains should be included on the maintenance schedule [21 CFR 1020.40(c)(9)(i)] to assure the system remains compliant with the performance standard.

Test and Measurement [21 CFR 1020.40(c)(1)(ii)]: *Compliance with the exposure limit in paragraph (c)(1)(i) of this section shall be determined by measurements averaged over a cross-sectional area of ten square centimeters with no linear dimension greater than 5 centimeters, with the cabinet x-ray system operated at those combinations of x-ray tube potential, current, beam orientation, and conditions of scatter radiation which produce the maximum x-ray exposure at the external surface, and with the door(s) and access panel(s) fully closed as well as fixed at any other position(s) which will allow the generation of x radiation.*

The standard states that compliance is determined by measurements averaged over a cross-sectional area of 10 square centimeters with no linear dimension greater than 5 centimeters. This means that when FDA makes a measurement to determine if a product complies with the emission limit, our test procedure will use a meter that meets that criteria or a test procedure that produces equivalent results. When selecting instrumentation and designing test procedures, manufacturers should be able to justify the equivalence of their results.

You should explain any correction factors used in your test and subsequent calculations in your procedure and your product report.

The measurement from the point of the highest emission reading must be less than the .5 mR emission limit [21 CFR 1020.40(c)(1)(i)]. An average of all emission measurements that is less than 0.5 mR in one hour is not sufficient to demonstrate compliance with the performance standard.

You should set the rejection limit for your test to determine compliance with the emission limit conservatively to account for the inherent error from measurement methods and

instrument accuracy. A rejection limit set at the emission limit might result in false certification of a product that does not comply but appeared to comply with the performance standard.

For your records, you need to write the measured exposure as a numerical measurement of the worst case emission from every system that you test. You must provide a summary of these test results as a histogram in your annual report [21 CFR 1002.30; see Guide for Filing Annual Reports for X-ray Components and Systems (July 1980) (http://www.fda.gov/cdrh/radhlth/pdf/xrcrpt0a.pdf)].

Instrumentation
Thin walled Geiger-Mueller (GM) meters are very useful in making a qualitative measurement to identify the location of the largest amount of radiation emission on a cabinet x-ray system's external surface. GM meters cannot be adequately calibrated for making quantitative measurements of x-ray emission. X-ray tubes produce radiation that contains a spectrum of different energies. GM meters do not have a linear response to radiation at different energies. GM meters respond to the number of ionizing events occurring in their measurement volume; however, they produce no information about the energy associated with each ionization event. Therefore, GM meters do not respond with equal count rates to equal exposure rates from photons of different energies. You should not assume that because a GM meter's readout scale is scribed in exposure rate units that the meter will accurately measure that quantity. More information about instrument selection criteria can be found in National Council on Radiation Protection and Measurements (NCRP) reports 57 and 112 (available from http://www.ncrponline.org).

Ion chambers are usually appropriate instruments for making quantitative measurements of radiation emission from cabinet x-ray systems. You should calibrate instruments as recommended by their manufacturers. Calibration should be done for an appropriate energy range for your product. Calibrating a meter with a Cesium 137 source (beta 511 keV and gamma 662 keV) and using it to measure a 120 kVp x-ray spectrum will lead to error that may be significant.

Floors [21 CFR 1020.40(c)(2)]**:** *A cabinet x-ray system shall have a permanent floor. Any support surface to which a cabinet x-ray system is permanently affixed may be deemed the floor of the system.*

When a space is occupied below the floor where a cabinet x-ray system is located, the floor may need additional shielding to assure that the emission below the floor meets the requirements of 21 CFR 1020.40(c)(1).

Ports and Apertures [21 CFR 1020.40(c)(3)]**:** *(i) The insertion of any part of the human body through any port into the primary beam shall not be possible. (ii) The insertion of any part of the human body through any aperture shall not be possible.*

This requirement is intended to prevent accidental and routine operator exposure to the primary x-ray beam. Under this provision, insertion of any body part into a port must not be

a standard operating procedure. This requirement is not intended to prevent people from intentionally attempting to defeat system safety features to reach the primary beam. Contorting to reach into, crawling into, or riding through the port into the system are examples of intentional defeat of safety systems.

You can use many means to meet this requirement. A system with a straight tunnel that is at least 36 inches from any port to the primary beam complies with this requirement. A system with a straight tunnel less than 36 inches from any port to the primary beam should have some means other than distance to make the primary beam difficult to reach. One example includes incorporating photoelectric sensors that turn on the beam when interrupted, and placed so they are unlikely to be triggered by someone in a normal posture reaching into the cabinet. Another example is locating system ports lower (near the floor) or higher (at head height) than is conventional. Also, integrating the system into a production line where the products being examined move fast enough to limit access to the port itself.

When your product uses ports [21 CFR 1020.40(b)(9)], you should describe the means used to prevent unintentional access to the primary beam in your product report. An isometric view of the cabinet system showing these features is often very helpful. Drawings or photos that show both a top down and side view can also make it much easier to explain your system's safety features.

Safety Interlocks [21 CFR 1020.40(c)(4)(i)]**:** *Each door of a cabinet x-ray system shall have a minimum of two safety interlocks. One, but not both of the required interlocks shall be such that door opening results in physical disconnection of the energy supply circuit to the high-voltage generator, and such disconnection shall not be dependent upon any moving part other than the door.* [Note: Safety interlock is defined in 21 CFR 1020.40(b)(11).]

The primary door interlock should be of conventional design. The second door interlock must physically disconnect the energy supply circuit to the high voltage generator. Physical disconnection means opening the energy supply circuit by removing a piece of the circuit. This is usually accomplished with a ‘knife-edge and finger stock’ or ‘plug and socket’ type connection. It is good practice to assure the primary interlock will remove power from the energy supply circuit before the physical disconnection occurs. Relays, micro switches, and ‘safety switches’ all contain moving parts and, therefore, cannot be used to satisfy the requirement that the physical disconnect interlock is "not dependent on any moving part other than the door."

[21 CFR 1020.40(c)(4)(ii)] *Each access panel shall have at least one safety interlock.*

Access panel interlocks are not required to physically disconnect the energy supply circuit.

[21 CFR 1020.40(c)(4)(iii)] *Following interruption of x-ray generation by the functioning of any safety interlock, use of a control provided in accordance with paragraph (c)(6)(ii) of this section shall be necessary for resumption of x-ray generation.*

After the triggering of any interlock, it must be necessary to use a control that is in compliance with the control regulations to resume x-ray generation. This requirement prevents the use of an interlock as a switch to turn x-ray production on.

[21 CFR 1020.40(c)(4)(iv)] *Failure of any single component of the cabinet x-ray system shall not cause failure of more than one required safety interlock.*

Ground Fault [21 CFR 1020.40(c)(5)]**:** *A ground fault shall not result in the generation of x-rays.*

A narrative text describing the possible ground fault failures and why they can not result in generation of x-rays is a good way to document compliance with this requirement [21 CFR 1002]. A simplified block electrical diagram to illustrate your analysis of possible ground faults is also helpful.

Controls and Indicators [21 CFR 1020.40(c)(6)]**:** *For all systems to which this section is applicable there shall be provided:*

[21 CFR 1020.40(c)(6)(i)] *A key-actuated control to insure that x-ray generation is not possible with the key removed.*

[21 CFR 1020.40(c)(6)(ii)] *A control or controls to initiate and terminate the generation of x-rays other than by functioning of a safety interlock or the main power control.*

[21 CFR 1020.40(c)(6)(iii)] *Two independent means which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second, in which case the indicators shall be activated for one-half second, and which are discernible from any point at which initiation of x-ray generation is possible. Failure of a single component of the cabinet x-ray system shall not cause failure of both indicators to perform their intended function. One, but not both, of the indicators required by this subdivision may be a milliammeter labeled to indicate x-ray tube current. All other indicators shall be legibly labeled "***X-RAY ON***".*

[21 CFR 1020.40(c)(6)(iv)] *Additional means other than milliammeters which indicate when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second, as needed to insure that at least one indicator is visible from each door, access panel, and port, and is legibly labeled "***X-RAY ON***".*

At least one indicator must be visible from each door, access panel, and port. These indicators must be legibly labeled "**X-RAY ON**". These additional indicators can not be milliammeters. The additional indicators must indicate when and only when x-rays are being generated. If the x-ray generation period is less than one-half second, the indicators must be activated for one-half second.

Some systems have standby modes where it is necessary to provide some current to the x-ray tube and some use capacitors to supply the tube. In these situations, there is not enough current for an x-ray tube to produce sufficient radiation for normal operation but there may be enough current to produce some radiation. It is appropriate to have the x-ray on indicators indicate whenever there is any current available to the x-ray tube. We also recommend that you have an additional indicator to show when x-rays are being produced at an operational level.

Additional Controls and Indicators [21 CFR 1020.40(c)(7)]**:** *For cabinet x-ray systems designed to admit humans there shall also be provided:*

(i) A control within the cabinet for preventing and terminating x-ray generation, which cannot be reset, overridden or bypassed from the outside of the cabinet.

(ii) No means by which x-ray generation can be initiated from within the cabinet.

(iii) Audible and visible warning signals within the cabinet which are actuated for at least 10 seconds immediately prior to the first initiation of x-ray generation after closing any door designed to admit humans. Failure of any single component of the cabinet x-ray system shall not cause failure of both the audible and visible warning signals.

(iv) A visible warning signal within the cabinet which remains actuated when and only when x-rays are being generated, unless the x-ray generation period is less than one-half second in which case the indicators shall be activated for one-half second.

(v) Signs indicating the meaning of the warning signals provided pursuant to paragraphs (c)(7) (iii) and (iv) of this section and containing instructions for the use of the control provided pursuant to paragraph (c)(7)(i) of this section. These signs shall be legible, accessible to view, and illuminated when the main power control is in the "on" position.

Warning Labels [21 CFR 1020.40(c)(8)]**:** *(i) There shall be permanently affixed or inscribed on the cabinet x-ray system at the location of any controls which can be used to initiate x-ray generation, a clearly legible and visible label bearing the statement:*
Caution: X-Rays Produced When Energized

(ii) There shall be permanently affixed or inscribed on the cabinet x-ray system adjacent to each port a clearly legible and visible label bearing the statement:
Caution: Do Not Insert Any Part of the Body When System is Energized--X-ray Hazard

Instructions [21 CFR 1020.40(c)(9)(i)]**:** *Manufacturers of cabinet x-ray systems shall provide for purchasers, and to others upon request at a cost not to exceed the cost of preparation and distribution, manuals and instructions which shall include at least the following technical and safety information: Potential, current, and duty cycle ratings of the x-ray generation equipment; adequate instructions concerning any radiological safety procedures and precautions which may be necessary because of unique features of the*

system; and a schedule of maintenance necessary to keep the system in compliance with this section.

In addition to major maintenance, such as when to change the x-ray tube, the schedule of maintenance should include items such as daily, weekly, monthly, and annual inspections to be carried out by the system operators. For example, your maintenance schedule could state, "Operators must check that all indicator lights function at least once a day." Another example would be periodic inspection of the condition of lead curtains for systems that use lead curtains. This regulation does not require that the maintenance schedule tell a system owner how to perform all of the required maintenance, only what maintenance must be done and how often.

Failure to provide a schedule of necessary maintenance is a common problem. If your product truly does not need any scheduled maintenance to keep it in compliance with the standard, you should explain why in your product report and provide a clear justification.

[21 CFR 1020.40(c)(9)(ii)] *Manufacturers of cabinet x-ray systems which are intended to be assembled or installed by the purchaser shall provide instructions for assembly, installation, adjustment and testing of the cabinet x-ray system adequate to assure that the system is in compliance with applicable provisions of this section when assembled, installed, adjusted and tested as directed.*

X-Ray Baggage [21 CFR 1020.40(c)(10)]**:** *X-ray systems designed primarily for the inspection of carry-on baggage at airline, railroad, and bus terminals, and at similar facilities, shall be provided with means, pursuant to paragraphs (c)(10) (i) and (ii) of this section, to insure operator presence at the control area in a position which permits surveillance of the ports and doors during generation of x-radiation.*

(i) During an exposure or preset succession of exposures of one-half second or greater duration, the means provided shall enable the operator to terminate the exposure or preset succession of exposures at any time.

(ii) During an exposure or preset succession of exposures of less than one-half second duration, the means provided may allow completion of the exposure in progress but shall enable the operator to prevent additional exposures.

X-ray baggage systems must have a means to ensure that the operator is present at the controls so that the operator can clearly view the ports and doors at all times during x-ray generation.

The phrase, "facilities similar to airline, railroad, and bus terminals," includes any place where members of the public walk up to an x-ray system for the purpose of security screening of their carried belongings. Therefore, cabinet x-ray security screening systems used in office buildings, court houses, and schools are also subject to this section [21 CFR 1020.40(c)(10)]. Cabinet x-ray systems that are in controlled access areas and are always loaded and unloaded by trained operators are not subject to this section.

Modification of a certified system [21 CFR 1020.40(d)] *The modification of a cabinet x-ray system, previously certified pursuant to 1010.2 by any person engaged in the business of manufacturing, assembling or modifying cabinet x-ray systems shall be construed as manufacturing under the act if the modification affects any aspect of the system's performance for which this section has an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the system in accordance with the provisions of 1010.2 and 1010.3 of this chapter.*

5. Records and Reports

Records [21 CFR 1002.30]
(a) Manufacturers of products listed under table 1 of 1002.1 shall establish and maintain the following records with respect to such products:
(1) Description of the quality control procedures with respect to electronic product radiation safety.

(2) Records of the results of tests for electronic product radiation safety, including the control of unnecessary, secondary or leakage electronic product radiation, the methods, devices, and procedures used in such tests, and the basis for selecting such methods, devices, and procedures.

(3) For those products displaying aging effects which may increase electronic product radiation emission, records of the results of tests for durability and stability of the product, and the basis for selecting these tests.

(4) Copies of all written communications between the manufacturer and dealers, distributors, and purchasers concerning radiation safety including complaints, investigations, instructions, or explanations affecting the use, repair, adjustment, maintenance, or testing of the listed product.

(5) Data on production and sales volume levels if available.

(b) In addition to the records required by paragraph (a) of this section, manufacturers of products listed [under table 1 of 1002.1] shall establish and maintain the following records with respect to such products:

(1) A record of the manufacturer's distribution of products in a form which will enable the tracing of specific products or production lots to distributors or to dealers in those instances in which the manufacturer distributes directly to dealers.

(2) Records received from dealers or distributors pursuant to 1002.41.

Reports [21 CFR 1002.1]

Reporting requirements and their applicability are covered in 21 CFR 1002.1 and the associated table. Generally, manufacturers of cabinet x-ray systems are subject to the reporting requirements.

Address for Submission of Reports

You should send product, supplemental, and annual reports to:

Center for Devices and Radiological Health
ATTN: Electronic Product Reports
Radiological Health Document Control (HFZ-309)
Office of Communication, Education, and Radiation Programs[3]
9200 Corporate Blvd
Rockville, MD 20850

Electronic Reporting Option

Alternatively, manufacturers may use the CeSub eSubmitter Software to prepare and submit reports and correspondence electronically. Download the CeSub eSubmitter Software and follow the instructions that accompany that software. More information on CeSub eSubmitter Software can be found on the FDA web site: http://www.fda.gov/cdrh/cesub/.

Product Report [21 CFR 1002.10]

Every manufacturer of a product or component requiring a product report as set forth in table 1 of 1002.1 shall submit a product report to the Center for Devices and Radiological Health; [ATTN: Electronic Product Reports; Radiological Health Document Control (HFZ-309); Office of Communication, Education, and Radiation Programs; 9200 Corporate Blvd; Rockville, MD 20850], prior to the introduction of such product into commerce.

Manufacturers of cabinet x-ray systems are required to submit a product report before entry of their product into commerce. A product report is intended to describe the product, how it complies with the performance standard, and the quality control and testing program that is used to certify the product [21 CFR 1002.10]. The format and contents of the product report are described in the reporting guide "Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40." (http://www.fda.gov/cdrh/radhlth/pdf/cabrpt01.pdf)

Supplemental Report [21 CFR 1002.11] *Prior to the introduction into commerce of a new or modified model within a model or chassis family of a product listed in table 1 of 1002.1 for which a report under 1002.10 is required, each manufacturer shall submit a report with respect to such new or modified model describing any changes in the information previously submitted in the product report. Reports will be required for changes that:*
(a) Affect actual or potential radiation emission.
(b) Affect the manner of compliance with a standard or manner of testing for radiation safety.

[3]The addresses for submission of reports and other information included in this guidance reflect the address for submission as of the date of this guidance; the addresses in the regulation are no longer current.

A supplemental report describes the changes between the model and / or procedures reported in a manufacturer's product report. The format and contents of a supplemental report follow the same format as the product report.

Annual Report [21 CFR 1002.13]
(a) Every manufacturer of products requiring an annual report as specified in table 1 of 1002.1 shall submit an annual report summarizing the contents of the records required to be maintained by 1002.30(a) and providing the volume of products produced, sold, or installed.

(b) Reports are due annually by September 1. Such reports shall cover the 12-month period ending on June 30 preceding the due date of the report.

(c) New models of a model family that do not involve changes in radiation emission or requirements of a performance standard do not require supplemental reports prior to introduction into commerce. These model numbers should be reported in quarterly updates to the annual report.

Manufacturers of cabinet x-ray systems must submit an annual report by September 1 of each year. The report covers all products produced and certified for sale in the U.S. between July of the previous year and June 30 of the submission year. The format and contents of the annual report are described in the reporting guide "Guide for Filing Annual Reports for X-Ray Components and Systems," (http://www.fda.gov/cdrh/radhlth/pdf/xrcrpt0a.pdf)

The annual reporting guide describes two test summary formats. In general, you should report radiation emission test results as a histogram based on numerical results of quantitative measurements. Most other tests and checks are appropriate to report as go / no-go tests.

6. Accident Reports and Recalls

Accident Reports
Reporting of accidental radiation occurrences [21 CFR 1002.20(a)]
Manufacturers of electronic products shall, where reasonable grounds for suspecting that such an incident has occurred, immediately report to the Director, Center for Devices and Radiological Health, all accidental radiation occurrences reported to or otherwise known to the manufacturer and arising from the manufacturing, testing, or use of any product introduced or intended to be introduced into commerce by such manufacturer. Reasonable grounds include, but are not necessarily limited to, professional, scientific, or medical facts or opinions documented or otherwise, that conclude or lead to the conclusion that such an incident has occurred.

Manufacturers of cabinet x-ray systems must immediately report accidental radiation occurrences (ARO) to the Director, Center for Devices and Radiological Health at:

Center for Devices and Radiological Health
ATTN: Accidental Radiation Occurrence Reports (HFZ-240)

Office of Communication, Education, and Radiation Programs
10903 New Hampshire Avenue
Silver Spring, MD 20993

Alternatively, manufacturers may use the CeSub eSubmitter Software to prepare and submit ARO reports and other correspondence electronically. Download the CeSub eSubmitter Software and follow the instructions that accompany the software. More information on CeSub eSubmitter Software can be found on the FDA web site: http://www.fda.gov/cdrh/cesub/.

[21 CFR 1002.20(b)] ARO *reports shall contain all of the following information where known to the manufacturer:*
(1) The nature of the accidental radiation occurrence;
(2) The location at which the accidental radiation occurrence occurred;
(3) The manufacturer, type, and model number of the electronic product or products involved;
(4) The circumstances surrounding the accidental radiation occurrence, including causes;
(5) The number of persons involved, adversely affected, or exposed during the accidental radiation occurrence, the nature and magnitude of their exposure and/or injuries and, if requested by the Director, Center for Devices and Radiological Health, the names of the persons involved;
(6) The actions, if any, which may have been taken by the manufacturer, to control, correct, or eliminate the causes and to prevent reoccurrence; and
(7) Any other pertinent information with respect to the accidental radiation occurrence.

If an incident involving an ARO is associated with a radiation safety defect or failure to comply with the performance standard and is reported pursuant to 21 CFR 1003.10 (see next section), a separate ARO report under 21 CFR 1002.20 is not required.

Recalls [21 CFR parts 1003 and 1004]

Discovery of a Problem and Notification [21 CFR 1003.10]
Any manufacturer who discovers that any electronic product produced, assembled, or imported by him, which product has left its place of manufacture, has a defect or fails to comply with an applicable Federal standard shall:
(a) Immediately notify the Secretary in accordance with 1003.20, and

(b) Except as authorized by 1003.30, furnish notification with reasonable promptness to the following persons:

(1) The dealers or distributors to whom such product was delivered by the manufacturer; and

(2) The purchaser of such product and any subsequent transferee of such product (where known to the manufacturer or where the manufacturer upon reasonable inquiry to dealers, distributors, or purchasers can identify the present user).

If a manufacturer discovers that any electronic product produced, assembled, or imported by him, has left its place of manufacture, and has a defect [21 CFR 1003.2] or fails to comply with an applicable performance standard, the manufacturer must immediately notify FDA following the requirements of 21 CFR 1003.20. Unless an exemption from notification [21 CFR 1003.30 and 1003.31] was requested and granted, the manufacturer shall also furnish notification, following the requirements of 21 CFR 1003.21, with reasonable promptness to the following persons:

- The dealers or distributors to whom such product was delivered by the manufacturer; and
- The purchaser of such product and any subsequent transferee of such product (where known to the manufacturer or where the manufacturer upon reasonable inquiry to dealers, distributors, or purchasers can identify the present user).

When FDA determines that a defect or failure to comply has occurred, FDA will notify the manufacturer in accordance with 21 CFR 1003.11.

Address all reports of radiation defect or failure to comply with a federal performance standard to:

Center for Devices and Radiological Health
ATTN: Notice of Defect or Noncompliance (HFZ-240)
Office of Communication, Education, and Radiation Programs
10903 New Hampshire Avenue
Silver Spring, MD 20993

Repurchase, Repairs, or Replacement [21 CFR part 1004]

Manufacturer's obligation to repair, replace, or refund cost of electronic products

(a) If any electronic product fails to comply with an applicable Federal standard or has a defect and the notification specified in 1003.10(b) of this chapter is required to be furnished, the manufacturer of such product shall;

(1) Without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedied; or

(2) Replace such product with a like or equivalent product which complies with each applicable Federal standard and which has no defect relating to the safety of its use; or

(3) Make a refund of the cost of the product to the purchaser.

(b) The manufacturer shall take the action required by this section in accordance with a plan approved by the Secretary pursuant to 1004.6.

The specifics of each type of corrective action are described in 21 CFR 1004. The manufacturer's corrective actions must be made in accordance with a plan approved by FDA [21 CFR 1004.6].

Address all Corrective Action Plans to:

Center for Devices and Radiological Health
ATTN: Notice of Defect or Noncompliance (HFZ-240)
Office of Communication, Education, and Radiation Programs
10903 New Hampshire Avenue
Silver Spring, MD 20993

7. Variances and Exemptions

Variances [21 CFR 1010.4]
Manufacturers that wish to produce a cabinet x-ray system that varies from any part of the performance standard must gain approval before the system can be sold in the United States. In order to gain this approval, an application for variance must be submitted. Variation from the standard can be granted if the product meets the following criteria:

- The cabinet x-ray system utilizes an alternate means for providing radiation safety or protection equal to or greater than that provided by other cabinet systems that meet all requirements of the standard, or
- The cabinet x-ray system performs a function or is intended for a purpose that could not be performed or accomplished if required to meet the cabinet x-ray system standards and a suitable means for assuring radiation safety or protection are provided, or
- One or more requirements of the standard are not appropriate, and suitable means for assuring radiation safety or protection are provided.

An original and four copies of the application for variance should be submitted to:

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

The application for variance should supply the information required by 21 CFR 1010.4(b). Historically, few variances have been granted for cabinet x-ray products.

Exemptions [21 CFR 1010.5]
In certain cases, when applied for, exemptions from the performance standard may be approved by the Director, Center for Devices and Radiological Health, if it is determined that the cabinet x-ray system is intended for use by departments or agencies of the United States and the system meets the following criteria:

- The acquiring agency prescribes procurement specifications for the cabinet x-ray system governing radiation emissions of the cabinet x-ray system and the cabinet x-ray system shall be used solely or predominantly by a department or agency of the United States.

- The cabinet x-ray system is intended for research, investigations, studies, demonstration, training, or for reasons of national security.

Applications for exemptions should include an original and two copies and should be addressed to:

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

You should not include information classified for reasons of national security in your application. The contents and criteria for an application for exemption and its approval are found in 21 CFR 1010.5.

Information related to an application for exemption may be requested from FDA under the Freedom of Information Act (5 U.S.C. 552) (FOIA). FDA will comply with the requirements of 21 CFR Part 20 on the disclosure of information.

8. Imports and Exports

Imports [21 CFR part 1005]
Import of a cabinet x-ray system will be refused entry into the United States unless there is affixed to the cabinet x-ray system a label or tag certifying compliance with the performance standard. Any systems refused entry will be destroyed or exported under regulations prescribed by the Secretary of the Treasury unless a timely and adequate petition for permission to bring the cabinet x-ray system into compliance is filed and granted. Further information about the importation process can be found on the FDA web site: http://www.fda.gov/cdrh/radhlth/eprc_imports_and_exports.html

Service of process on manufacturers [21 CFR 1005.25]
(a) Every manufacturer of electronic products, prior to offering such product for importation into the United States, shall designate a permanent resident of the United States as the manufacturer's agent upon whom service of all processes, notices, orders, decisions, and requirements may be made for and on behalf of the manufacturer as provided in section 360(d) of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263h(d)) and this section. The agent may be an individual, a firm, or a domestic corporation. For purposes of this section, any number of manufacturers may designate the same agent.

(b) A manufacturer designating an agent must address the designation to the Center for Devices and Radiological Health; ATTN: Designation of Agent (HFZ-240); Office of Communication, Education, and Radiation Programs; 10903 New Hampshire Avenue, Silver Spring, MD 20993. It must be in writing and dated; all signatures must be in ink. The designation must be made in the legal form required to make it valid and binding on the manufacturer under the laws, corporate bylaws, or other requirements governing the making of the designation by the manufacturer at the place and time where it is made, and the

persons or person signing the designation shall certify that it is so made. The designation must disclose the manufacturer's full legal name and the name(s) under which the manufacturer conducts the business, if applicable, the principal place of business, and mailing address. If any of the products of the manufacturer do not bear his legal name, the designation must identify the marks, trade names, or other designations of origin which these products bear. The designation must provide that it will remain in effect until withdrawn or replaced by the manufacturer and shall bear a declaration of acceptance duly signed by the designated agent. The full legal name and mailing address of the agent must be stated. Until rejected by the Secretary, designations are binding on the manufacturer even when not in compliance with all the requirements of this section. The designated agent may not assign performance of his function under the designation to another.

Exports [21 CFR 1010.20]
The performance standards prescribed in this subchapter shall not apply to any electronic product which is intended solely for export if:

(a) Such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and

(b) Such product meets all the applicable requirements of the country to which such product is intended for export.

Once a product has been exported, it may not be possible to return it to the U.S., even if that return is only for service and then re-export. Products that are labeled for export, and therefore not certified, will be refused entry to the U.S.

FDA does not issue export certificates for non-medical cabinet x-ray systems.

9. Getting More Information

You can get more information about our requirements for cabinet x-ray systems from our electronic product radiation control web page http://www.fda.gov/cdrh/radhealth/.

If you have any questions about this guidance, contact Daniel Kassiday, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 10903 New Hampshire Avenue, Silver Spring, MD 20993 or daniel.kassiday@fda.hhs.gov.